DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0430 Expiration Date: April 30, 2009 See OMB Statement on page 2.

FOR	FDA I	USE	ONL	Y.
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APPLICATION NUMBER

APPLICANT INFORMATION								
NAME OF APPLICANT				DATE OF SUBMISSION				
TELEPHONE NO. (Include Area Code)				FACSIMILE (FAX) Number (Include Area Code)				
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):			,	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE				
PRODUCT DESCRIPTION				47.01.1				
NEW DRUG OR ANTIBIOTIC APPLICATION NUM	•	GICS LICENSE A			• •	• ,		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name)		PROF	ROPRIETARY NAME (trade name) IF ANY					
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NA	AME (If any)			CC		CODE NAME (If any)		
DOSAGE FORM:	STRENGTHS:	STRENGTHS:			ROUTE	OUTE OF ADMINISTRATION:		
(PROPOSED) INDICATION(S) FOR USE:								
, , , , , , , , , , , , , , , , , , , ,								
APPLICATION INFORMATION								
APPLICATION TYPE (check one) NEW DRUG APPLICATI	ON (NDA 21 CED	214 50)	BBDE	VIATED NEW D		PLICATION (ANDA, 21 CFR 314.94)		
	ICS LICENSE API	, —			100 AFF	LICATION (ANDA, 21 OF A 314.94)		
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IF AN ANDA OR 505(b)(2) IDENTIFY THE REFEI	. , ,	,	505 (THAT	, , ,	OR THE	SUBMISSION		
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Name of Drug Holder of Approved Application								
TYPE OF SUBMISSION (check one)	DICINIAL ADDILICATION	ON [7 4845	IDMENT TO A DEA	IDING ADE	DECUMPANCION		
PRESUBMISSION (CHECK OHE) O ANNUAL F	RIGINAL APPLICATION		_	NDMENT TO A PEN DESCRIPTION SU		_		
	HEMISTRY MANUFA				FFLEIVIEIN	OTHER		
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:								
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY						Prior Approval (PA)		
REASON FOR SUBMISSION								
PROPOSED MARKETING STATUS (check one) PRESCRIPTION PRODUCT (Rx) OVER THE COUNTER PRODUCT (OTC)								
NUMBER OF VOLUMES SUBMITTED THIS APPLICATION IS PAPER PAPER AND ELECTRONIC ELECT				PAPER AND ELECTRONIC ELECTRONIC				
ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.) Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.								
Ourse Defended which which did in the Applications INDs NDs DMs Edd(), IDE DME 1995 (1995)								
Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)								

This	application contains the following items: (Check all that apply)
	1. Index
	2. Labeling (check one)
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (I)(3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. Financial Information (21 CFR Part 54)
	20. OTHER (Specify)
CERTIF	FICATION
•	to update this application with new safety information about the product that may reasonably affect the statement of contraindications,

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

- 1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
- 2. Biological establishment standards in 21 CFR Part 600.
- 3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
- 4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
- 5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
- 6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
- 7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate. **Warning:** A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT

TYPED NAME AND TITLE

DATE

ADDRESS (Street, City, State, and ZIP Code)

Telephone Number

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Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (HFD-143) Central Document Room 5901-B Ammendale Road Beltsville, MD 207052-1266 Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research (HFM-99) 1401 Rockville Pike Rockville, MD 20852-1448

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